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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,836	11/28/2000	Shila Jalali		6157

9629 7590 05/04/2004

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EXAMINER	
MUTSCHLER, BRIAN L	
ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,836	JALALI ET AL.	
	Examiner	Art Unit	
	Brian L. Mutschler	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-117* is/are pending in the application.

4a) Of the above claim(s) *33-117* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20010228; 20021209*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-32, in Paper No. 20040312 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claim 1 is objected to because of the following informalities:

a. In claim 1, lines 9-10 are duplicates of lines 7-8 and should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10-13, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the conductive fluid member" in line 1. There is insufficient antecedent basis for a single conductive fluid member. Claim 9 recites "an array of conductive fluid members" in lines 1-2. Therefore, the relationship between the single conductive fluid member and the array of the conductive fluid members is

unclear. The same limitation also appears in claim 11, and the same rejection applies to dependent claims 12 and 13.

Claim 26 recites the limitation "the gradient" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the phrase be changed to --the gradient material--, as recited in claim 25. The same limitation also appears in claim 27.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 6-9, 14-16, 19, 21-24, and 28-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Mitsuhashi et al. (US 2004/0069635).

Regarding claim 1, Mitsuhashi et al. teach a system for separating charged molecules comprising a sample plate with a plurality of sample wells, a capture matrix comprising a diffusion-inhibiting layer (both the gel and the insulating wall with a microspot) and a binding layer (dialysis membrane), a first electrode capable of being placed in electrical contact with at least one sample well at the bottom end of the sample well, and a second electrode capable of being placed in electrical contact with

the top end of the sample well, where both electrodes are connected to a power supply (figs. 23, 5A, and 5B; par. [0024] and [0062]).

Regarding claims 6-8, the electrodes may comprise plate electrodes or an array of pin electrodes (figs. 2, 3, 5A and 5B).

Regarding claim 9, the second electrode may comprise an array of conductive fluid members in electrical contact with at least one electrode, i.e., the second electrode **150** is formed in a separate chamber filled with buffer **80** (figs. 1-3).

Regarding claims 14 and 15, the electrodes are integrated into the sample plate (fig. 2; par. [0017] and [0020]).

Regarding claim 16, the diffusion layer (gel **25**) is disposed between the binding layer (membrane **75**) and the top opening of the well (fig. 5A; par. [0098]-[0099]).

Regarding claim 19, the binding layer is a dialysis membrane that binds the molecule of interest non-specifically (par. [0058]-[0059]).

Regarding claims 21-24, the diffusion-inhibiting layer comprises materials such as polyacrylamide, agarose, or cellulose (par. [0074]).

Regarding claims 28-30, the capture matrix is comprised of an insulating wall (thickness = 0.3 mm = 0.03 cm) and a dialysis membrane (thickness = 0.01 mm to 10 mm or 0.1 mm to 0.5 mm = 0.001 cm to 1 cm or 0.01 cm to 0.05 cm), which yields a total thickness of 0.031 cm to 1.03 cm or 0.04 cm to 0.08 cm (par. [0055] and [0059]).

Regarding claims 31 and 32, the sample plate is comprised of a plurality of layers having voids that form the sample wells, and the capture matrix is sandwiched between the outer two plates (fig. 2).

Since Mitsuhashi et al. teach all of the structural limitations recited in the instant claims, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsuhashi et al. (US 2004/0069635), as applied above to claims 1, 6-9, 14-16, 19, 21-24, and 28-32, and further in view of Applicant's admissions made in the disclosure.

Mitsuhashi et al. disclose a system having the limitations recited in claims 1, 6-9, 14-16, 19, 21-24, and 28-32 of the instant invention, as explained above in section 6.

Regarding claims 3-5, Mitsuhashi et al. disclose that the system may use 96 well plates, 384 well plates or larger (par. [0062]).

The system of Mitsuhashi et al. differs from the instant invention because Mitsuhashi et al. do not disclose that the sample plate is a rectangular plate measuring 8.5 cm by 11 cm, as recited in claim 2, or that the sample plate comprises 1536 sample wells, as recited in claim 5.

As disclosed in the instant disclosure, the standard size of 96-, 384- and 1536-well plates is 8.5 cm by 11 cm (see page 10, lines 9-10). Well plates are standardized

so that they can be efficiently used with existing equipment, such as analyzers and pipettes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the plates of Mitsuhashi et al. to use a standardized plate size as taught by the Applicant's admissions because the standard plate size enables the system to be usable with existing, standardized equipment.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsuhashi et al. (US 2004/0069635), as applied above to claims 1, 6-9, 14-16, 19, 21-24, and 28-32, and further in view of WO 98/10277, herein referred to as WO '277.

Mitsuhashi et al. discloses a system having the limitations recited in claims 1, 6-9, 14-16, 19, 21-24, and 28-32 of the instant invention, as explained above in section 6. The system of Mitsuhashi et al. comprises an arrangement of electrodes in buffer solution contained within separate compartments (figs. 1-3).

The system of Mitsuhashi et al. differs from the instant invention because Mitsuhashi et al. do not disclose that the conductive fluid member is a hydrogel comprising a conductive fluid contained within a solid tubular support, as recited in claim 10.

WO '277 discloses a similar system for separating charged molecules, wherein each electrode is contained within its own electrode chamber that is separated from the sample chamber by a protective layer or separation medium, including a membrane, a

polymer, or a gel (page 9, lines 3-6). The protective layer or separation medium prevents the molecules being separated from entering the electrode chamber.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electrode assembly of Mitsuhashi et al. to use a separation medium as taught by WO '277 because the separation medium will prevent migration of the material into the electrode compartment.

10. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsuhashi et al. (US 2004/0069635), as applied above to claims 1, 6-9, 14-16, 19, 21-24, and 28-32, and further in view of WO 98/10277 and Nelson et al. (U.S. Pat. No. 6,074,827).

Mitsuhashi et al. discloses a system having the limitations recited in claims 1, 6-9, 14-16, 19, 21-24, and 28-32 of the instant invention, as explained above in section 6. The system of Mitsuhashi et al. comprises an arrangement of electrodes in buffer solution contained within separate compartments (figs. 1-3).

The system of Mitsuhashi et al. differs from the instant invention because Mitsuhashi et al. do not disclose that the conductive fluid member is a hydrophilic diffusion barrier comprising a conductive fluid contained within a solid tubular support, as recited in claim 11, or that the hydrophilic diffusion barrier consists of porous glass or a paper filter, as recited in claims 12 and 13, respectively.

WO '277 discloses a similar system for separating charged molecules, wherein each electrode is contained within its own electrode chamber that is separated from the

sample chamber by a protective layer or separation medium, including a membrane, a polymer, or a gel (page 9, lines 3-6). The protective layer or separation medium prevents the molecules being separated from entering the electrode chamber.

Nelson et al. disclose a method and system for enriching charged molecules and teach that glass frits or agarose gel can be used to retain material (col. 6, lines 14-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electrode assembly of Mitsuhashi et al. to use a separation medium as taught by WO '277 because the separation medium will prevent migration of the material into the electrode compartment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have further modified the system to use a hydrophilic diffusion barrier such as glass frit as taught by Nelson et al., which is similarly capable of blocking the flow of material. Similarly, filter paper is another commonly used barrier to prevent the migration of molecules.

11. Claims 17, 18, 20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsuhashi et al. (US 2004/0069635), as applied above to claims 1, 6-9, 14-16, 19, 21-24, and 28-32, and further in view of Nelson et al. (U.S. Pat. No. 6,074,827).

Mitsuhashi et al. discloses a system having the limitations recited in claims 1, 6-9, 14-16, 19, 21-24, and 28-32 of the instant invention, as explained above in section 6.

The system of Mitsuhashi et al. differs from the instant invention because Mitsuhashi et al. do not teach the following:

a. The binding layer binds the molecule of interest specifically, as recited in claim 17.

b. The binding layer comprises an affinity-binding material selected from the group consisting of antibodies, streptavidin, and avidin, as recited in claim 18.

c. The binding layer comprises a material selected from the group consisting of metal chelate resins, ionic resins, cationic resins, polyvinylidine fluoride, nitrocellulose, charged nylon, and porous glass, as recited in claim 20.

d. The diffusion-inhibiting material is a gradient material, as recited in claim 25.

Regarding claims 17 and 18, Nelson et al. disclose a system for separating charged molecules and teach the use of an enrichment channel to contain the molecule of interest (col. 11, line 66 to col. 12, line 42). Nelson et al. teach the use of both specific and generic binding media, such as membranes, for the enrichment region (col. 7, line 24 to col. 8, line 23). The enrichment region contains an enrichment media can be an affinity chromatography material in which a binding member, such as an antibody, is covalently bound to a matrix (col. 5, line 66 to col. 6, line 29). Nelson et al. also teach the use of streptavidin, as a specific binding material (col. 8, lines 3-6).

Regarding claim 20, Nelson et al. teach that suitable capture media for proteins includes anion and cation exchange resins, as well as nitrocellulose (col. 8, lines 10-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the membrane of Mitsuhashi et al. to use a specifically-binding material as taught by Nelson et al. because a material that specifically bind the molecule of interest will minimize other materials that would be trapped by a non-specific binding material. It would also have been obvious to use the specific materials recited in claims 18 ad 20 because Nelson et al. teach that the capture media used depends on the molecule of interest and that such capture media includes streptavidin, antibodies, nitrocellulose, and anionic and cationic resins.

Regarding claim 25, Nelson et al. teach that electrophoretic gel media can be used to concentrate the molecule of interest and that a gradient condenses the material into a narrow band (col. 7, lines 24-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the diffusion inhibiting material of Mitsuhashi et al. to use a gradient material as taught by Nelson et al. because a gradient material condenses the material of interest into a narrow band.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (571) 272-1341. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

blm
April 30, 2004

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